

REMARKS

Claims 98-110 and 112-120 remain in this application. Claims 100, 102, 107, 108, 114-119 are withdrawn from prosecution. Claims 98 and 109 are currently amended and claim 111 is cancelled. Claim 120 is new.

Claim 98 is currently amended to recite a sense repressor gene encoding a protein. Support for this amendment is found in the specification at e.g. pages 53-54. Basis for claim 120 may be found in e.g. claims 98, 109 and Example 6 in the specification. Claim 109 has been amended merely to clarify the description of oncogenes 1, 2 and 4 of *Agrobacterium*.

Concerning Amendments to the Specification

The Examiner has indicated that the substitute pages of the specification submitted with the Preliminary Amendment of March 21, 2001 have not been entered because the instant application is not a national phase of a PCT application under 35 USC § 371 but is instead a continuation of a PCT with a separate U.S. specification. Therefore, the Examiner maintains that the rules for entry of amendments to the specification under 37 CFR § 1.121(c), apply and any amendments made to the PCT specification during its prosecution are not automatically made in the instant continuation application.

Accordingly, by way of the present amendments, the Article 34 Amendments are entered into the instant specification in accordance with 37 CFR § 1.121, (revised format).

Concerning the Requirement for a Fresh Oath or Declaration

The Examiner asserts that a new Oath or Declaration is required in view of alterations in the specification which have not been initialed and/or dated as required by 37 CFR § 1.52(c), and points to page 65 as an example.

Applicants understand the Examiner to be referring to the Article 34 Amendments filed during the international phase on March 21, 2001.

Applicants respectfully request that the requirement of a further Oath or Declaration be withdrawn for the following reasons.

The combined Declaration and Power of Attorney documents were executed by the inventors in September 2001, after the filing of the instant application. The Declarations specifically identify the instant application as amended on June 22, 2001, and also International Application No. PCT/CA99/01223, of which the instant application is a continuation. Thus, the Declarations on file clearly contemplate and encompass the PCT Article 34 amendments made during the International phase and re-entered herein.

Applicants respectfully submit that Rule 1.52(c) applies in the circumstance where the executed Declaration is filed together with the application papers, and alterations are made in the application papers. Rule 1.52(c) helps ensure that the application papers are not altered after they have been reviewed by the inventor and the inventor has signed the Declaration.

In the instant case, the Declaration was executed subsequent to filing, with full knowledge of the Article 34 Amendments, even if there were technical deficiencies in the manner of entering these Amendments.

Reconsideration and withdrawal of the requirement for a new Declaration are therefore respectfully requested.

Concerning 35 USC § 112

Claims 98-99, 101, 103-106 and 109-113 stand rejected under 35 USC § 112, first paragraph, for insufficiency of written description. The Examiner acknowledges (Office Action, page 3, line 19) that the specification provides a written description of a “sense repressor gene encoding a protein.”

Claims 98-99, 101, 103-106 and 109-113 stand rejected under 35 USC § 112, first paragraph, as lacking enablement. The Examiner acknowledges (page 4, last two lines) that the specification is enabled for claims limited to a method using “a sense repressor gene encoding a protein.”

Applicants respectfully traverse these rejections and submit that the specification provides a full written description of various suitable repression strategies that are known in the art, and which could be used in the practice of the present invention. Applicants submit that the skilled person could utilize such repression techniques in the practice of the instant invention, without undue experimentation. Nevertheless, in order to advance prosecution,

Applicants have amended claim 98 to recite a "sense repressor gene encoding a protein"; subject matter that the Examiner has acknowledged is described and enabled in the instant specification.

Applicants reserve the right to prosecute the subject matter of the original claims in one or more continuing or divisional applications.

Concerning 35 USC § 102

Claims 98-99, 103 and 109-113 stand rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 5,689,041 to Mariani *et al.* Claims 98-99, 103-104 and 109-113 stand rejected under 35 USC § 102(e) as being anticipated by U.S. Patent No. 5,723,763 to Mariani *et al.* Applicants note that the '763 patent is a division of the '041 patent and both are referred to herein collectively as "Mariani *et al.*" Claims 98-99, 103-104, 106 and 109-113 also stand rejected under 35 USC § 102(b) as being anticipated by WO 97/44465 (Monsanto).

Applicants respectfully traverse these rejections. The instant invention concerns a technology completely unrelated to that described by Mariani *et al.* and Monsanto.

In the instant invention, undesired outcrossing or introgression of alien germplasm is prevented by providing, at separate, independently segregating loci, a repressible lethal gene, and a sense repressor gene encoding a protein capable of repressing the activity of the gene product of the repressible lethal gene. Repression of the lethal gene is dependent on the continuing presence in the plant of the repressor gene. If the repressor gene is lost e.g. during independent segregation in an outcross, the repressible lethal gene will no longer be repressed, and the plant containing the repressible lethal gene will die. If a trait of interest is closely linked to the repressible lethal gene, the survival of a plant containing the trait of interest will therefore be dependent on the continued presence in the plant of the repressor gene. This system provides a means to control the flow of the trait of interest in a population. The mutually independent segregation of the repressor gene and the repressible lethal gene will result in loss of repression and lethality during an outcross or introgression. The continued presence of the repressible-lethal-gene-and-the-repressor gene is required for the normal phenotype.

In contrast, both Mariani *et al.* and Monsanto involve technologies wherein a "normal" phenotype is rescued by the introduction of a new gene activity. Mariani *et al.* involves a technology wherein a ribonuclease, specifically barnase, is selectively expressed in the male or female sex organs of plants to effect male- or female-sterility. Sterility is then overcome by the introduction of a "foreign restorer gene", which encodes barstar. The barstar gene offsets the presence of barnase, such that the male-specific or female-specific fertility is restored.

Similarly, Monsanto concerns the rescue of a germination-positive phenotype in plants. Specifically, a DNA sequence encoding acyl CoA oxidase (ACOX) under the control of a germination-specific or germination-enhanced promoter interferes with a lipid metabolism in the seed, preventing germination. A second DNA sequence, encoding an antisense ACOX mRNA is under the control of an inducible promoter, so that when the inducible promoter is induced, antisense mRNA is produced, thereby inhibiting translation of ACOX, and the germination-positive phenotype is restored. Applicants note that Monsanto does not actually contain working examples of restoration of the germination-positive phenotype by induction of transcription of the antisense mRNA.

The instant claims recite the step of "selecting for a genetically modified plant descended from our derived from at least one of the plurality of whole plants by determining incorporation and mutually independent segregation of the repressor gene and the repressible lethal gene within the genetically modified plant".

Applicants respectfully submit that neither Mariani *et al.* nor Monsanto teach or suggest this limitation. In the instant invention, independent segregation provides a means by which loss of the repressor function results in plant death, preventing the undesired contamination of other plant species with a trait of interest from a genetically modified plant. In contrast, independent segregation would serve no purpose in the technologies described in Mariani *et al.* and Monsanto and would indeed be contrary to the purposes of those technologies.

In Mariani *et al.*, independent segregation and loss of the barstar gene would result in an undesired reversion to the male- or female-specific sterility. In Monsanto, independent segregation and loss of the DNA encoding the antisense ACOX transcript would result in reversion to the germination-negative phenotype and germination could no longer be

selectively induced. Hence, independent segregation is entirely contrary to the purposes of either Mariani *et al.* or Monsanto.

Applicants respectfully submit that in Mariani *et al.* and Monsanto, any independent integration and segregation of the trans genes would be undesired and accidental or unintended consequence of the methods described therein. Applicants respectfully submit that the mere possibility that independent segregation occurs in Mariani *et al.* and Monsanto is insufficient to establish inherency. To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by the person of ordinary skill...inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Schreiber*, 128 F. 3d 1473, 1477, 44 USPQ 2d 1429, 1431 (Fed. Cir. 1997) (emphasis added).

Certainly, if independent segregation occurred in Mariani *et al.* or Monsanto, this was accidental and unwitting, and such accidental, unintended and unappreciated production of a product or process does not constitute anticipation. *Tilghman v. Proctor* 102 US 707 (United States Supreme Court 1881).

Moreover, the Examiner states that progeny could be evaluated for independence by calculating genetic ratios of the progeny exhibiting the particular traits. As discussed above, this is insufficient to establish inherency. The possibility that progeny could be evaluated for independence does not constitute anticipation. To establish inherency, it is necessary that the missing descriptive matter is necessarily present in the thing described in the reference. In the instant case, there is no evidence that plants were selected by determining incorporation and mutually independent segregation of the repressor gene and the repressible lethal gene within a genetically modified plant as instantly claimed. Even if this was a possibility, this does not rise to the level of anticipation. Reconsideration and withdrawal of the rejections of the claims for lack of novelty are therefore respectfully requested.

Concerning 35 USC § 103

Claims 98-99, 101, 103, 106 and 109-113 stand rejected under 35 USC § 103(a) as being unpatentable over both Mariani *et al.* references. Claims 98-99, 101, 103-106 and 109-113 also stand rejected under 35 USC § 103(a) as being unpatentable over Monsanto.

Applicants respectfully traverse these rejections. The instant claims recite selecting for a genetically modified plant by determining incorporation unmutually independent segregation of the repressor gene and the repressible lethal gene within the genetically modified plant. As discussed above, Mariani *et al.* and Monsanto do not teach independent segregation or a selection step based on the presence of independent segregation, as instantly claimed.

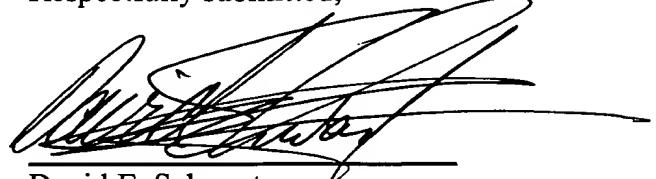
Even if, in some instances, the transgenes of Mariani *et al.* and Monsanto indeed segregated independently, then this was not discussed in the references and there is no suggestion or motivation in the references to use a selection step based on independent segregation, as instantly claimed.

Moreover, as discussed above, independent segregation and loss of the fertility-restorer gene or germination-restorer gene would be contrary to the purposes of Mariani *et al.* and Monsanto, respectively. Selecting plants on the basis of determining incorporation and mutually independent segregation of a repressor gene and a repressible lethal gene would therefore be contrary to the intended purpose of the technology described by Mariani *et al.* and Monsanto and would render it unsatisfactory for its intended purpose. Where a modification would render a reference being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Applicants therefore respectfully submit that the instant claims are unobvious over Mariani *et al.* and Monsanto. Reconsideration and withdrawal of the rejections of the claims are therefore respectfully requested.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,



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